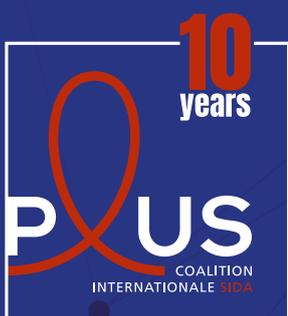


MIND THE GAP

HCV POLICIES
VERSUS
COMMUNITY
EXPERIENCES
2018



HIV/HCV DRUG AFFORDABILITY PROJECT

This study was carried out as part of the Coalition PLUS HIV/HCV Drug Affordability project, funded by Unitaid. Since its launch in 2015, the project has established partnerships with 15 local civil society organizations in seven countries: Brazil, Colombia, India, Indonesia, Malaysia, Morocco, and Thailand. Through outreach at the community level and engagement in the domestic policy dialogue, project partners promote increased awareness, access to diagnostics, and access to treatment.

FOREWORD

Across all income settings, hepatitis C continues to impose a significant burden on persons living with HIV. The WHO estimated in 2016 that 2.3 million people living with HIV (PLHIV) are co-infected with hepatitis C virus (HCV), of whom 1.3 million are persons who inject drugs (PWID). Despite the emergence of a revolutionary treatment nearly four years ago, it remains unclear to what extent—or even which direction—burdens of co-infection have since changed. Some countries seem to have made substantial initial progress against the epidemic, others remain near an equilibrium of new infections and successfully treated cases, and several appear to face a rising population of co-infected individuals. However, in far too many settings, baseline epidemiological information is too limited to accurately measure the burden, while monitoring of the cascade is also insufficient or altogether absent.

In spite of weak systems of surveillance, qualitative trends in the HCV response can be clearly identified. In fact, we see that many of the most important barriers to elimination efforts are not unique to hepatitis C, but rather reflect broader challenges the health system encounters in addressing a wide range of diseases. These obstacles include, but are not limited to: insufficient awareness, limited access to diagnostics, overly-centralized service delivery, inefficient referral systems along the continuum of care, exorbitant medicine prices, inadequate financing, stigma towards most-at-risk populations, and policies that criminalize behaviors of certain most-at-risk populations.

For those engaged in the fight against HIV, many of these issues sound familiar. Prior to the influx of generic ARVs and massive international funding, the HIV response faced similar bottlenecks at similar stages along the continuum. And while many of these bottlenecks have since been reduced and HIV cascades have improved, global progress on HIV diagnosis has remained particularly stubborn. Yet of the many lessons that the HCV response can draw from the HIV response, perhaps the most important is the essential role of community engagement. After all, the success of the HCV policy response is not only a function of available resources, but also the extent that most-at-risk populations are able to access health services and empowered to participate in both the design and implementation of the response. Unfortunately, such groups are often marginalized, rather than empowered. In the case of PWID and MSM, their very behaviors are not only stigmatized but frequently criminalized.

While there may be several paths to elimination, it must be emphasized that any successful path must target elimination in most-at-risk communities, particularly co-infected populations. After all, the prioritization of most-at-risk communities is not only a public health

imperative, it is also the shortest road to elimination in nearly all settings. Those governments with policies that discriminate against or criminalize most-at-risk populations are lengthening the journey. In doing so, they are putting at risk both the achievement of elimination and the lives of countless citizens.

The observations above should remind us that elimination of HCV epidemics are not a *fait accompli*. In fact, among HCV intervenors it is expected that Member States' progress updates toward the 2020 targets (to be presented by the 2021 World Health Assembly) will provide a sober illustration of this point. At present, the WHO is engaging Member States in preparation of the reporting process on 2020 targets. These quantitative measurements will provide important evaluations of responses at country level. However, it is crucial to complement this strategic information with structured qualitative information, which is instrumental to both explaining progress and identifying opportunities to improve further.

A core element of a qualitative analysis of a given disease response is the voice of affected communities. For health services and health policy to be people-centered, it must be informed by patient perspectives. Through structured focus group discussions with 240 community members and interviews with 51 healthcare workers, the study detailed by this report explored a wide range of experiences. Across sites in five countries, several messages emerged: gaps in awareness, gaps in affordability, gaps in healthcare workforces, gaps in funding, and gaps in political will. Collectively, these gaps explain the divergence of policies on paper and their realization in practice; in turn, such divergence helps explain the gap between the progress made by countries toward elimination, and the progress they need to have made by now to be on track to 2020 and 2030 targets.

With the arrival of DAAs, one of the most important gaps has been closed; we now have the technology to eliminate hepatitis C. If the global community were to do so, it would mark the first time that a major infectious disease has ever been eliminated through the use of a medicine. Whether we succeed or not will ultimately be, at the end of the day, a question of political will.

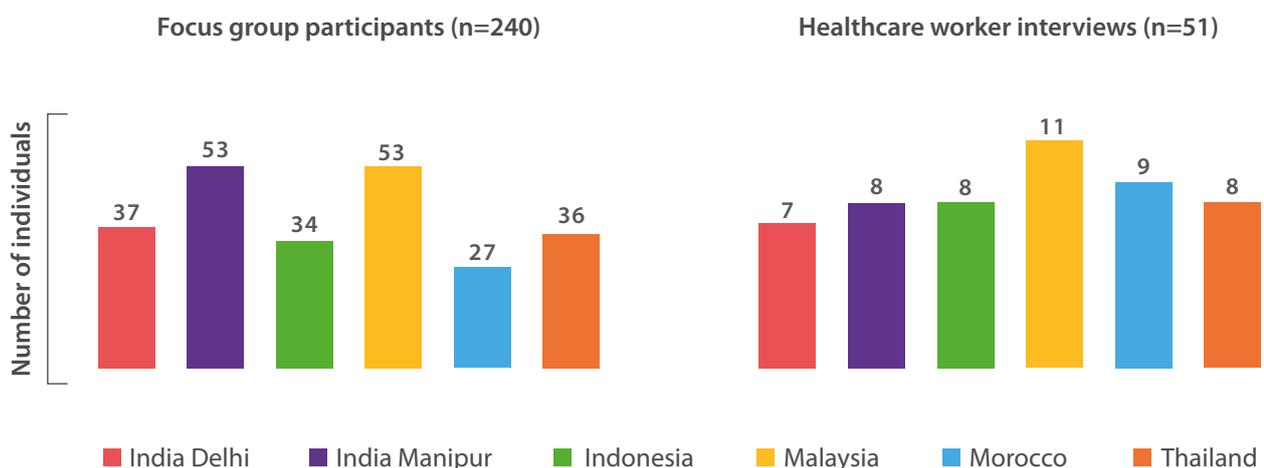
Paraphrasing a Winston Churchill quote, we can say that in the HCV response, we are no longer at the beginning, nor are we near the end. Rather, we are at the end of the beginning. There is much work left to do to reach elimination, and it will only be achieved if the community is an essential participant in the process.

Hakima Himmich
President of Coalition PLUS
July 2018

EXECUTIVE SUMMARY

In 2016, WHO Member States adopted a global strategy to eliminate hepatitis C by 2030. This resolution followed shortly after the arrival of medicines that have revolutionized hepatitis C (HCV) treatment. Known as direct-acting antivirals (DAAs), these medicines offered people living with hepatitis C (PLHCV) a safe, highly-effective cure. To the public health community, DAAs presented an unprecedented opportunity: a means to eliminate an infectious disease through a medicine. Yet while the goal of elimination can appear simple enough on paper, the design and implementation of programs to achieve it require further elaboration of country-level strategies and corresponding budgets. In turn, the translation of strong policies to successful practice at ground-level will prove the key catalyst to elimination. The exploration of such a gap—between policy commitments on paper and the reality of their implementation in practice—represented the focus of a study conducted by Coalition PLUS and its partners. Through over 40 hours of structured focus group discussions with 240 at-risk individuals [primarily people who inject drugs (PWID) and people living with HIV/AIDS (PLHIV)] and PLHCV, the survey provided communities an opportunity to voice their perspectives and experiences. To further strengthen ground-level insights into the HCV response, 51 healthcare workers providing HCV services were also interviewed.

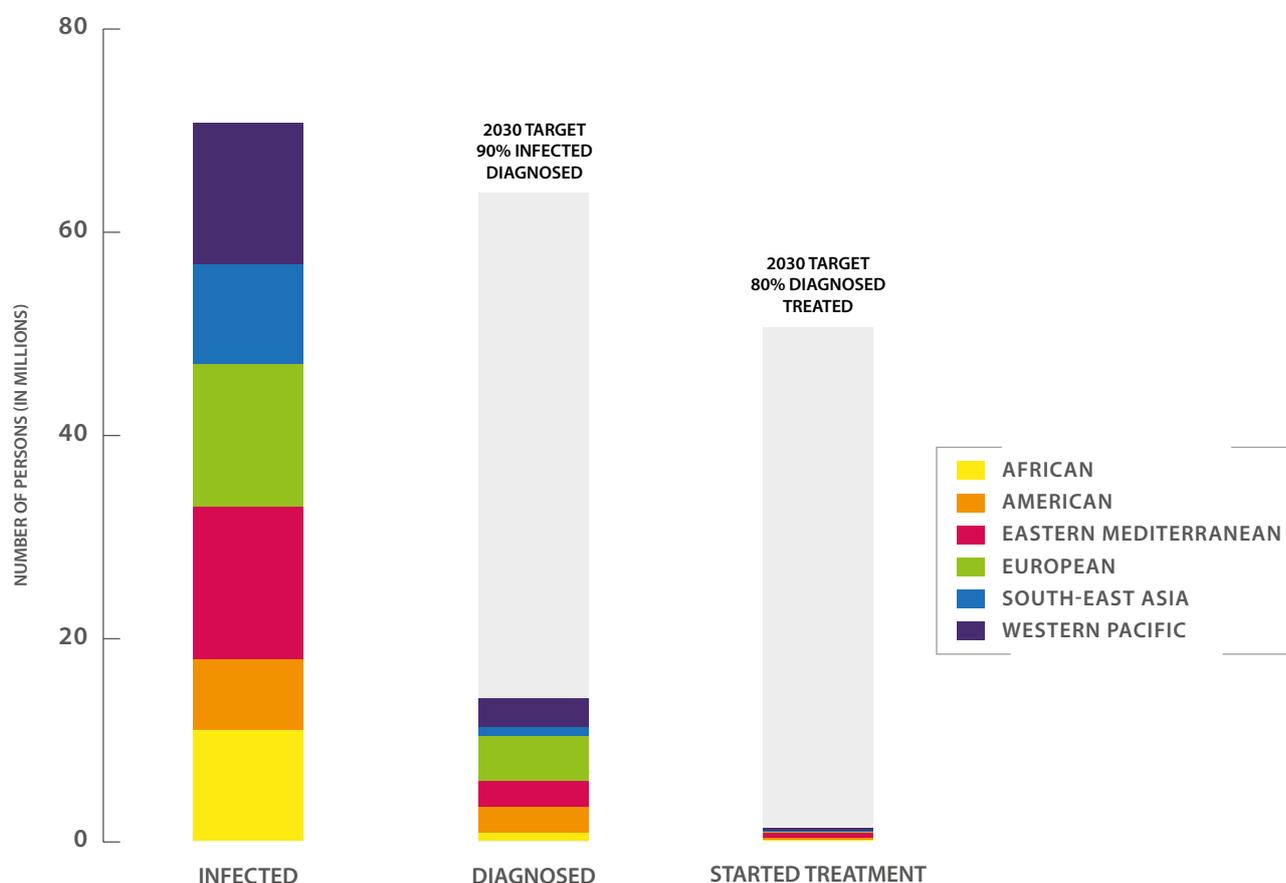
FIGURE 1 - STUDY PROFILE



This report complements the evaluations of hepatitis responses conducted by fellow stakeholders. One particular inspiration was the WHO's recent development of country response profiles through a survey on a checklist of indicators of structure (e.g., policy decisions), input (e.g., budget allocation) and process (e.g., implementation of WHO guidelines). To complement the WHO's top-down macro-level overview of HCV responses, the Coalition PLUS survey provides a bottom-up micro-level evaluation of the HCV response at selected sites in five middle-income countries: India, Indonesia, Malaysia, Morocco, and Thailand.

As an explanatory and qualitative survey, the findings and recommendations serve to inform the response in the countries involved in the study. In addition to highlighting potential gaps between policy adoption and policy implementation/coverage, this evaluation exposed a variety of thematic gaps in awareness, health workforce capacity, service affordability, funding, and political will. Analysis of these gaps contributes qualitative context to complement the strategic information that governments have accumulated. In particular, it aims to nourish the dialogue that country updates on the 2020 targets—to be presented at the World Health Assembly in 2021—will surely provoke. Four years away from 2020, the latest global estimations of progress toward those goals (Figure 2 below) show that most regions face a massive gap between present cascades and regional/global targets.

FIGURE 2 - CASCADE OF CARE FOR PEOPLE LIVING WITH HCV INFECTION BY WHO REGION, 2015 BASELINE



*WHO estimates that 1.5 million people started DAA treatment in 2016, compared to around 1 million in 2015; with regards to incidence, WHO estimated 1.75 million new HCV infections in 2015.

Source: Global Hepatitis Report 2017. Geneva: World Health Organization; 2017.

If the raw data of the cascade serves to describe the response, this survey contributes to the process of explaining it by providing a robust sample of individual stories behind the numbers.

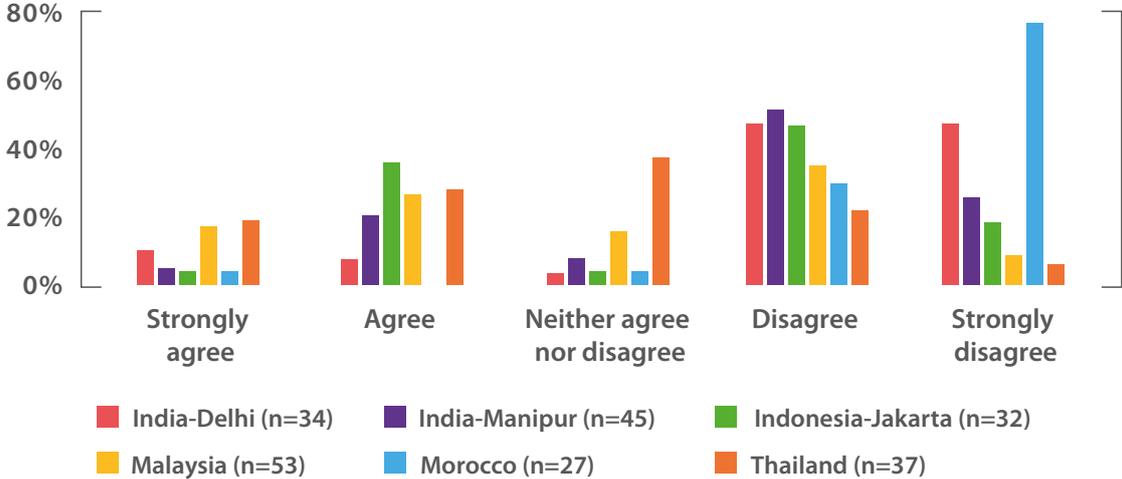
In synthesizing these accounts, two overarching themes emerged from the study, both of which are tied to the **lengthy timeline and logistical complexity of completing diagnosis and treatment**. Those themes are insufficient HCV awareness and insufficient HCV capacity.

INSUFFICIENT AWARENESS

Awareness campaigns are needed to increase understanding of HCV prevention, diagnosis, and treatment. This call was echoed by both the focus group participants (see Figure 3) and healthcare workers. As discussions of *awareness* often employ the word in an overly vague manner, it is important to clarify exactly what sort of information is required. Survey participants emphasized that awareness-raising must deliver knowledge that is **accessible, accurate, and actionable**. While the scope of information needed will vary according to key stakeholders—i.e. patients, healthcare workers, and policy-makers—the report demonstrates that all these groups currently operate under a **significant deficit of information**. To address this gap, comprehensive awareness-raising will require investments. **Resources must be allocated to trainings, education materials, public campaigns, and counseling**. Furthermore, it is important to note that the knowledge deficits of stakeholder groups are often linked. Improved healthcare

worker awareness on HCV—as well as improved understanding of how to effectively communicate such knowledge—would significantly increase patient awareness. On this point, many focus group participants and healthcare workers highlighted the importance of the quality of patient-healthcare worker interaction. Where present, it is a crucial catalyst on the pathway. Yet many participants indicated that both the limited HCV training and limited counseling time afforded to healthcare workers presented obstacles to maximizing this interaction. In particular, the need for more extensive training was expressed by many of the healthcare workers interviewed during the study. In fact, several healthcare workers interviewed for this study demonstrated a lack of knowledge of the full diagnosis protocol, and many (notably in India) indicated the absence of a policy at their facilities for implementing HCV screening tests.

FIGURE 3 - THE PUBLIC IS GENERALLY AWARE OF HEPATITIS C



INSUFFICIENT CAPACITY

The survey demonstrated that the continuum of care—the pathway of services a patient must follow—presents a myriad of complex barriers for patients. **In turn, the length, cost, and complexity of current pathways have a major impact on not just individuals, but on the efficiency and scalability of HCV responses. The process must be simplified.** In some cases, such simplification should apply to the protocol guidelines (i.e. the prescribed pathway of screening, viral load confirmation, liver staging, treatment, etc). But

more broadly, the simplification needs to consider the actual logistical pathway that patients must navigate (i.e. how/where/when one can link to services). **To achieve such simplification, HCV service capacity must be expanded.** Existing limitations in capacity (due to lack of training or due to protocol restrictions) often lead to excessive centralization at tertiary facilities; in turn, such centralization not only saturates capacity, but—as figures 4 and 5 show—imposes significant indirect costs on the patient.

FIGURE 4 - TIME OF TRAVEL TO HEALTH FACILITY FROM MY RESIDENCE OR PLACE OF WORK WAS A BARRIER TO GOING FOR TREATMENT

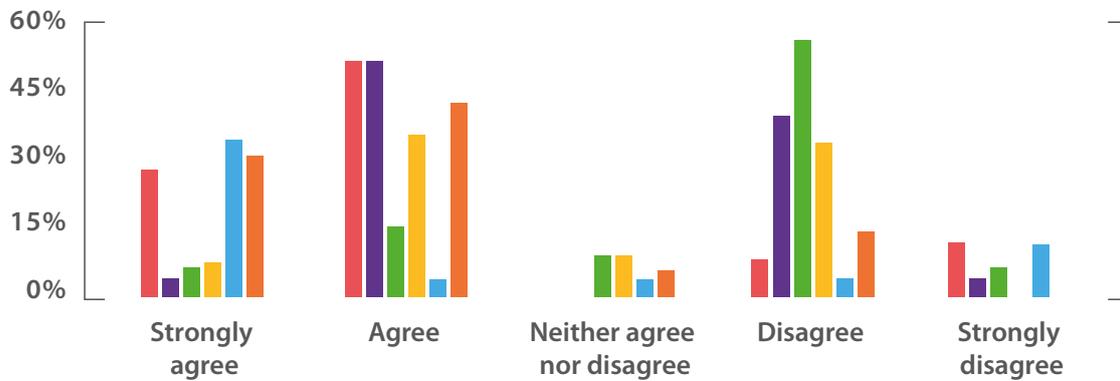
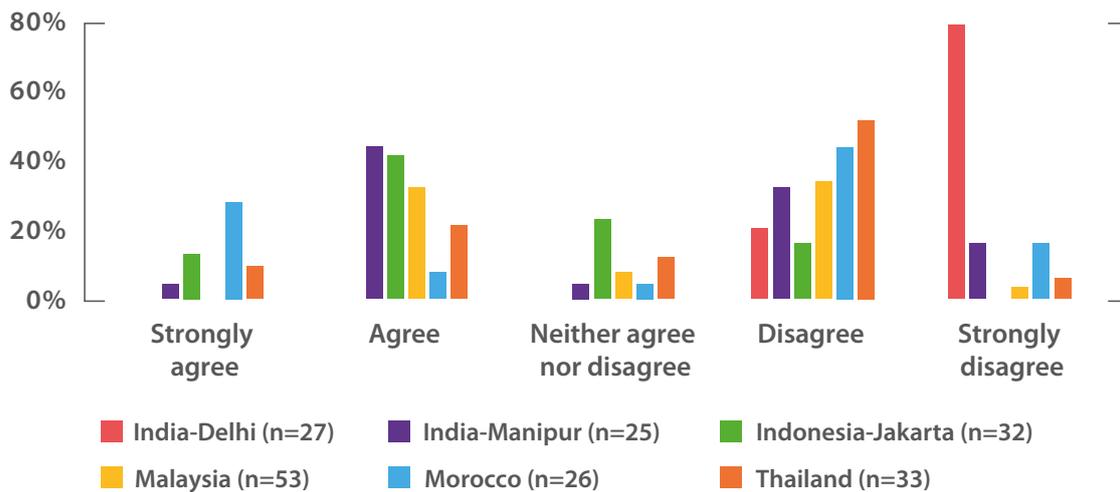


FIGURE 5 - THE WAITING TIME AT HEALTH FACILITIES IS NOT VERY LONG



Through decentralization/integration of services and normalization of quality counseling, the direct and indirect costs of the pathway could be drastically reduced. To accomplish this, **there is a clear need for a wider cadre of healthcare workers to be eligible and trained for delivery of HCV services.** In fact, the strain generated by restrictions on the scope of healthcare workers eligible to deliver HCV services will become even greater bottlenecks for countries that are in the process of expanding HCV programs. **It is therefore imperative that protocols are simplified, service delivery becomes more streamlined, and task-shifting is adopted.**

While the barrier presented by the pathway’s logistical complexity may be exacerbated by the limited awareness of relevant information, even those fully knowledgeable of the process may face significant barriers of time and expense. Far too many individuals confront both obstacles, and far too many countries face the vicious cycle of insufficient awareness and insufficient capacity. Given this interaction, both points should be addressed simultaneously.

While these dynamics are illustrated by responses to the questionnaire that was completed by focus group participants, these issues were explored in far greater detail during the focus group discussions and through interviews with healthcare workers. This more elaborate feedback is captured in the report chapters for each country.

SIMPLIFICATION OF CARE: THE NEED FOR A SHORTER AND STRAIGHTER PATHWAY

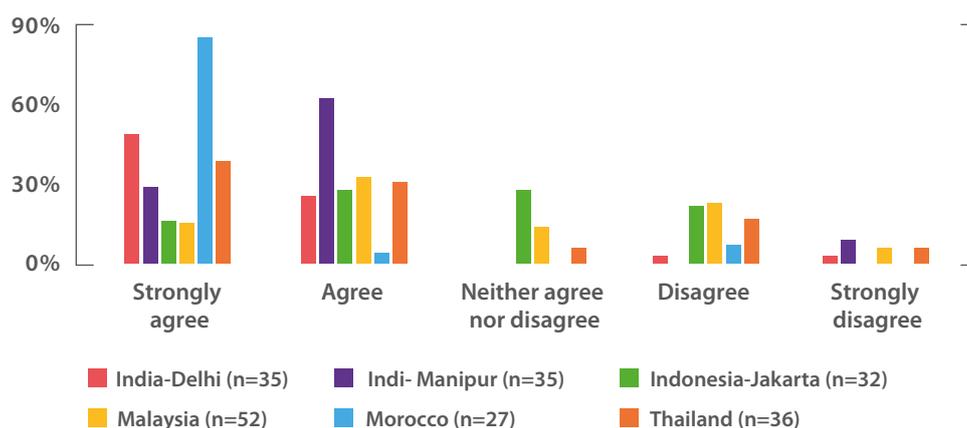
DIAGNOSIS

At present, the stages to complete diagnosis are frequently costly, long, and complex. Each factor alone could lead to voluntary patient drop out or involuntary delays in the pathway. Often, patients must confront all three barriers.

The cost of diagnosis includes both indirect and direct costs. Indirect costs (such as travel expenses, foregone wages, childcare, etc) can represent a significant barrier, particularly where travel or waiting times are substantial. While these indirect costs were

broadly acknowledged by focus group participants as important obstacles, the healthcare workers interviewed did not identify this barrier. In addition to these “hidden” expenses, direct testing costs (i.e. fees charged by the facility for testing services) must be financed out-of-pocket in several of the countries examined in this survey; the impact of such barriers is highlighted in Figure 6. Taken together, these costs can introduce important disincentives or obstacles to completing the diagnosis pathway.

FIGURE 6 - THE COST OF DIAGNOSTIC STEPS WAS A BARRIER TO GETTING DIAGNOSED



The excessive length of the process is often the product of delays due to a limited number of appointment spaces and/or delays in returning test results. For example, participants in several groups cited delays of 2-4 weeks to receive appointments, and another 2-4 weeks to receive test results. If test results are delivered in person, the individual may then need to schedule an appointment (another possible delay) for another trip to the clinic. These delays could also be due to limited capacity of diagnostic infrastructure. In Manipur, for example, blood samples were sent several hours by plane to Delhi for confirmation testing. In the absence of such sample transport networks, the individuals themselves must travel long distances to facilities.

The fragmentation of testing services was also highlighted by focus group participants. Many of the healthcare workers interviewed confirmed this point, as many of their facilities only offered one stage of the diagnosis pathway (i.e. most often it was the screening test). The need to visit multiple facilities not only complicates the pathway, it increases costs (due to greater number of visits) and the risk of referral problems.

TREATMENT

While the focus group discussions and healthcare worker interviews focused heavily on earlier parts of the pathway (i.e. awareness and diagnosis), several points on treatment emerged.

As programs scale up treatment and services reach more rural areas, the logistical complexity of DAA supply will increase and, in turn, stock-outs could become more important. And in fact, the study found cities where supply of DAAs is already an issue. For example, Indonesian participants expressed concern over stock-outs. Moreover, recent communication with Indian colleagues has revealed that stock-outs are also a present concern in Delhi. It should be noted that both—Jakarta and Delhi—are capital cities. One may expect that supply chain management could become even more troublesome in less populated settings.

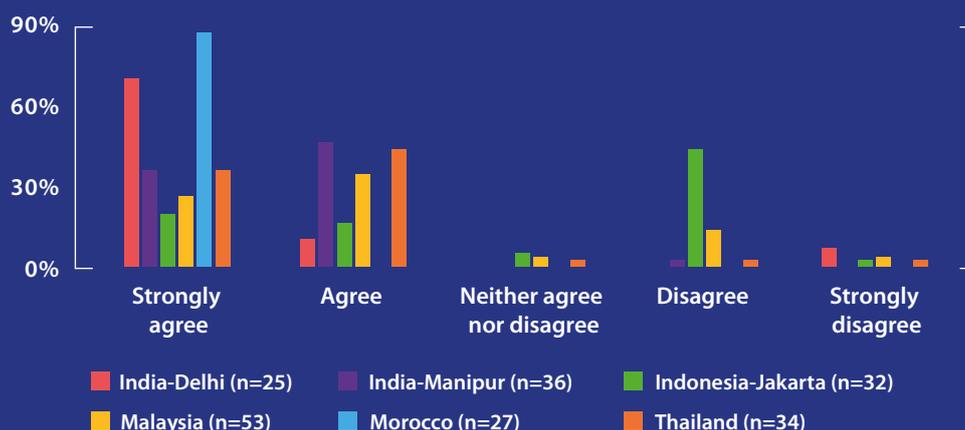
Focus groups also highlighted the potentially burdensome procedure to access free treatment offered by government programs. In Delhi, for example, free treatment currently requires monthly visits to a specific hospital for prescription re-fills, where queues for a re-fill can take hours. In Indonesia, monthly re-fills required the presentation of accompanying blood test results. In fact, it emerged from multiple discussion groups that, in practice, access to “free” services was often limited by the capacity at those public facilities providing them. Many participants explained that they were even advised by healthcare workers at such facilities to pursue services in the private sector in order to expedite diagnosis or treatment.

Thai participants also highlighted concerns over highly restrictive treatment criteria, as Thai doctors and health professionals have often imposed a requirement that patients should be “clean” (not consuming recreational drugs) for 6 months before they could start treatment. This requirement sometimes went beyond the use of banned drugs and included the use of alcohol, tobacco and similar substances.

Moreover, as figure 7 highlights, the survey provided confirmation of the extent that the cost of treatment represents a major factor for treatment access.

Fortunately, many countries included in the survey are in the process of expanding treatment programs. In turn, **the improved affordability and tolerability of DAAs will be crucial to communicate**; after all, the pre-DAA treatment for hepatitis C was notoriously expensive and came with intense side effects, a point acknowledged by several participants during the survey. Awareness campaigns should address this legacy to avoid misconceptions about new treatment.

FIGURE 7 - THE COST OF THE MEDICINES WAS A BARRIER TO GETTING TREATED



ADDRESSING LOSS-TO-FOLLOW-UP

As a result of the myriad barriers highlighted above, many patients will drop out or become stuck in the continuum-of-care pathway. In such cases, there did not appear to be a strong retention system in several sites. In Manipur, for example, only one of the eight healthcare workers interviewed indicated

that they follow up with NGOs or through other relevant channels if a patient drops out of the system during diagnosis or treatment.

Not only must the follow-up be more consistent, but there must also be opportunities to re-link to the pathway. Such channels would likely require funding for additional human resources. **Loss-to-follow-up and re-linkage to care are two crucial issues that policy-makers must highlight as priorities to address.**

DECENTRALIZATION OF SERVICES, “ONE-STOP SHOPS”, AND SERVICE INTEGRATION

The centralization of HCV services may stem from several factors: lack of healthcare worker capacity (due to limited training or protocol restrictions on eligibility), limited diagnosis infrastructure (e.g. access to viral load machines and/or sample transport networks), or absence of strong supply chain management. Whatever the reason, the resulting fragmentation introduces significant barriers. The report elaborates on these obstacles further; the issues highlighted above—as well as those illustrated by Figures 8 and 9—provide a glimpse of the impact of fragmentation and capacity saturation. Taken collectively, **the study highlights that services must be brought closer to the patients and the complexity of the pathway must be reduced.** Simplification and decentralization are thus necessary to both expand capacity and to expand access. In particular, the problems are further exacerbated for individuals living in rural settings, who often face systematically higher indirect costs due to limited HCV services outside major cities. In fact, the distance of rural patients from key services in the pathway raises significant questions about the equity of access to HCV services in many countries.

In urban centers where one-stop clinics (providing all services of the pathway) are feasible, such

models should be explored. In more rural areas, one-stop clinics should also be evaluated, but where not feasible, a streamlined path of decentralized services should be evaluated. For example, the Punjab (India) government—working in collaboration with Project ECHO and leading Indian hepatologists—has implemented one such model; through a recently launched collaboration with FIND, they are exploring models of further decentralization. Such demonstration projects are important catalysts to improved models of service delivery.

Integration of HCV services with other programs should also be improved. For at-risk populations that regularly link with HIV-related or harm reduction services, such specialist facilities should—where feasible—offer HCV services. At the very least, education about HCV—the disease, protocol, and services—should be available. If possible, HCV testing should be provided and should be accompanied by counseling. For these approaches to be successful, a wider cadre of healthcare workers (notably generalists) must be permitted to prescribe and/or administer testing and treatment.

FIGURE 8 - THE COSTS OF TIME OFF WORK HAD AN IMPACT ON MY ABILITY TO COMPLETE DIAGNOSIS OR TREATMENT

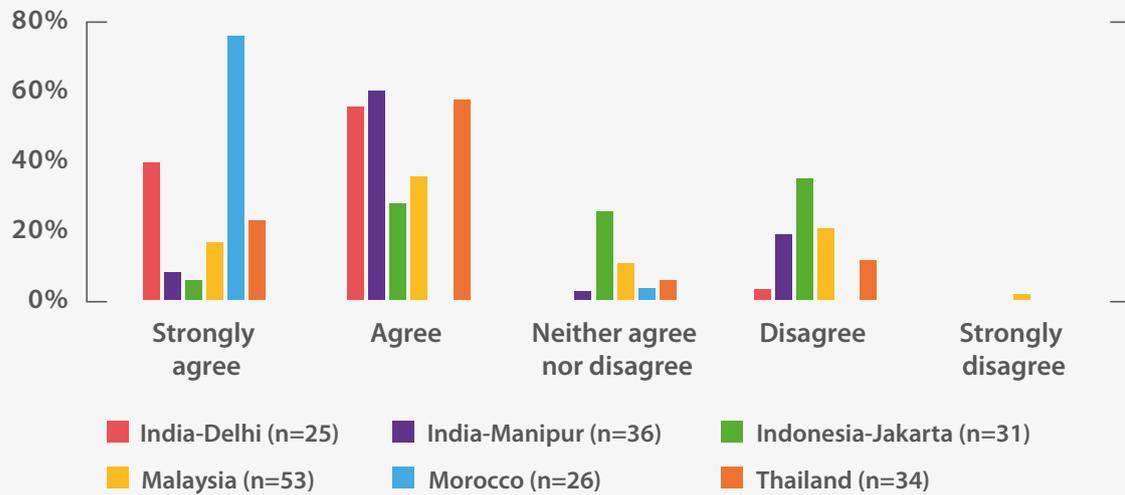
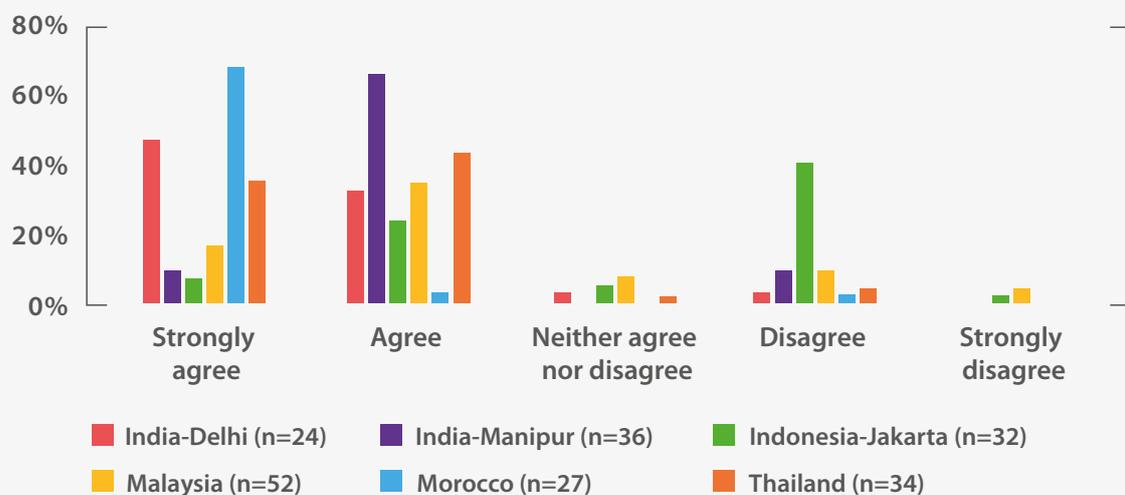


FIGURE 9 - OTHER OUT-OF-POCKET COSTS (E.G. FOR TRAVEL, OR CARE FOR FAMILY) HAD AN IMPACT ON MY ABILITY TO COMPLETE TREATMENT



THE NEED FOR RESEARCH ON AWARENESS-RAISING AND SERVICE DELIVERY MODELS

This report identifies several areas for further research to explore. Research questions stemming from this study could focus on: How to best educate stakeholders? How to improve patient-healthcare worker interaction? How to re-integrate those lost-to-follow-up? How to address structural barriers to access (notably those stemming from indirect costs and out-of-pocket expenses)?

Many of these questions could be further monitored in future iterations of this survey; future iterations could also explore a broader geographic range of sites. Moreover, the fact that several of the countries involved in this survey have recently launched significant expansions of their HCV response (notably India, Thailand, and Malaysia) means that survey responses related to treatment may—in those cases—be soon outdated. However, access to treatment will need to be monitored. In fact, reduced barriers to DAA access only reinforce the importance of the messages on awareness and diagnosis.

It should be noted that limitations of sample size and geographic reach must inform excessive extrapolation of the survey's results. In this context, it should also be added that as most survey participants were drawn from urban areas, the study may very well underestimate gaps in awareness and service capacity. For example, the Indonesian focus groups took place in Jakarta, a capital city that benefits from a greater concentration of the country's HCV-related services than other cities, let alone more rural areas or peripheral islands. As important disparities in healthcare workforce (especially of specialists) and laboratory infrastructure often exist between major cities and rural areas, a potential implication would be the following: while this survey revealed important gaps in HCV services at study sites, those gaps could be even larger in many settings in the five countries included in this report.

CONCLUSION



An increasing number of countries have adopted encouraging HCV policies (guidelines, strategies, action plans). However, in transforming those policies from paper to practice, **this report highlights the fact that many hepatitis programs face key gaps in the implementation and scale-up of their HCV response.** In synthesizing the experiences and perspectives captured by the survey, two themes emerged: **insufficient awareness** and **insufficient HCV service capacity.** At present, the dynamic between the two creates a vicious cycle. Fragmentation in the continuum of care contributes to the lengthy timeline and logistical complexity of the patient pathway; in turn, limited capacity of healthcare workers means that many PLHCV are not engaged in counseling/testing by healthcare workers, while those who have tested positive often find the rest of the pathway difficult to navigate.

For policy implementation to be successful, the HCV response needs to be adequately prioritized and funded by governments. Appropriate resources will be necessary to launch successful awareness campaigns, to train a wider cadre of existing healthcare workers on HCV, to support HCV counseling, to implement testing strategies, and to procure the required medicines.

Much of the recent attention on hepatitis C has focused—justifiably so—on this last point: namely, the exorbitant price tags that originator companies have placed on DAAs. Indeed, the past two years have reinforced that access to medicines is an absolutely necessary component of a robust HCV response. In many countries facing high prices (most notably in middle-income countries of Latin America and Eastern Europe/Central Asia), the lack of access seems to have stalled the launch of ambitious programs. Yet in those countries where generic medicines are affordable, this survey has demonstrated that accessibility of treatment is not sufficient in itself. It must be complimented by the adoption of policies targeting awareness, prevention, and diagnosis. In particular, the study highlighted that efforts to increase access to treatment must go beyond medicine prices to take into account the entire range of costs: the direct costs of out-of-pocket expenses, as well as the indirect costs of travel and lost wages.

Some of these barriers may be addressed by hepatitis programs; however, many of the obstacles will require the engagement of other government stakeholders. In fact, one may argue that the effort to eliminate hepatitis C provides a litmus test of the key pillars of any health system. After all, the success of the HCV response will depend on the integration of people-centered services, the capacity of the diagnostic infrastructure, access to medicines, the strength of the health workforce, the quality of strategic information systems, and universal health coverage. This study touches on all of these points and, in the process of highlighting existing gaps, makes recommendations for improvements.

The technical and technological means to achieve elimination are available now, the challenge is to more effectively mobilize them. To be successful, that process will require the engagement of communities in both the identification of bottlenecks and the identification of solutions. In documenting community perspectives on key obstacles and key recommendations, this study recognizes and demonstrates the importance of community input on policy responses. They are the individuals most affected and—along with HCV service providers—the individuals who possess the most direct first-hand experience of policy implementation in practice. Communities are therefore best-placed to issue the call heard so often in this report: we must not wait until the 2020 targets are reported to react to existing gaps. We must take action now!

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COALITION PLUS

Founded in 2008, Coalition PLUS is an international coalition of community-based organizations against AIDS and viral hepatitis. Coalition PLUS is now present worldwide with 100 partners in 40 countries. Through the 14 member organizations of our Board, the decision-making process involves associations from both the Global North and Global South. With our community-based approach, we advocate for people who live with HIV/viral hepatitis and key populations to be systematically involved in the design, implementation and evaluation of the healthcare programs that directly affect them. Through our action and our 6 regional platforms, we aim to strengthen the capacity of our members and partners, as well as to expand the space for their participation in important dialogues.

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